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*Attorneys for Plaintiffs*
*Dow Pharmaceutical Sciences, Inc.*
*and Valeant Pharmaceuticals North America LLC*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| DOW PHARMACEUTICAL SCIENCES, INC. and VALEANT PHARMACEUTICALS NORTH AMERICA LLC,<br><br>Plaintiffs,<br><br>v.<br><br>PERRIGO UK FINCO LIMITED PARTNERSHIP, PERRIGO ISRAEL PHARMACEUTICALS LTD., L. PERRIGO COMPANY, and PERRIGO COMPANY,<br><br>Defendants. | Civil Action No.: _______________<br><br>*Document Electronically Filed* |

# COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Dow Pharmaceutical Sciences, Inc. (“Dow”) and Valeant Pharmaceuticals North America LLC (“Valeant”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Perrigo UK FINCO Limited Partnership (“Perrigo UK”), Perrigo Israel Pharmaceuticals Ltd. (“Perrigo Israel”), L. Perrigo Company (“L. Perrigo”), and Perrigo

Company (collectively, "Perrigo" or "Defendants") allege as follows:

**THE PARTIES**

1. Plaintiff Dow is a corporation organized and existing under the laws of California having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

2. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

3. Upon information and belief, Perrigo UK is a limited partnership of the United Kingdom with a place of business at Wrafton, Braunton, Devon, EX33 2DL, United Kingdom. Upon information and belief, Perrigo UK is a wholly-owned subsidiary of Perrigo Company plc.

4. Upon information and belief, Perrigo Israel is an Israeli corporation with a place of business at 29 Lehi Street, Bnei Brak 51200, Israel. Upon information and belief, Perrigo UK is a wholly-owned subsidiary of Perrigo Company.

5. Upon information and belief, L. Perrigo is a Michigan corporation with a place of business at 8 Campus Dr. Fl 2 Parsippany, New Jersey 07054. Upon information and belief, Perrigo UK is a wholly-owned subsidiary of Perrigo Company.

6. Upon information and belief, Perrigo Company is a Michigan corporation with a place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Upon information and belief, Perrigo UK is a wholly-owned subsidiary of Perrigo Company plc.

7. Upon information and belief, defendants Perrigo UK, Perrigo Israel, L. Perrigo and Perrigo Company are affiliates of each other, and are wholly-owned subsidiaries of Perrigo Company plc.

## NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 8,288,434 ("the '434 patent") and 9,504,704 ("the '704 patent") arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Perrigo's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic benzoyl peroxide and clindamycin phosphate topical gel (3.75%; Eq. 1.2% Base) ("Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel").

## JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, this Court has jurisdiction over Perrigo UK. Upon information and belief, Perrigo UK is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products developed or manufactured by Perrigo Company. Upon information and belief, Perrigo UK directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Perrigo UK purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this Court has jurisdiction over Perrigo Israel. Upon information and belief, Perrigo Israel is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products

developed or manufactured by Perrigo Company. Upon information and belief, Perrigo Israel directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Perrigo Israel purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this Court has jurisdiction over L. Perrigo. Upon information and belief, L. Perrigo is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products developed or manufactured by Perrigo Company. Upon information and belief, L. Perrigo directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, L. Perrigo purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, this court has jurisdiction over Perrigo Company. Upon information and belief, Perrigo Company is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Perrigo Company directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Perrigo Company purposefully has conducted and continues to conduct business in this judicial district.

14. Upon information and belief, Perrigo UK, Perrigo Israel, L. Perrigo and Perrigo Company each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell and distribute generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

15. Perrigo Israel has admitted to, consented to, or has not contested the jurisdiction of this Court in at least three prior District of New Jersey actions: *Meda Pharmaceuticals Inc. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 14-cv-1241; *Dow Pharmaceutical Sciences, Inc. et al. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 13-cv-6922; and *Meda Pharmaceuticals Inc. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 12-cv-361.

16. L. Perrigo has admitted to, consented to, or has not contested the jurisdiction of this Court in at least six prior District of New Jersey actions: *AstraZeneca AB et al. v. L. Perrigo Company et al.*, Civil Action No. 15-cv-1057; *Senju Pharmaceutical Co., Ltd. et al. v. L. Perrigo Company et al.*, Civil Action No. 15-cv-337; *Meda Pharmaceuticals Inc. v. L. Perrigo Company et al.*, Civil Action No. 14-cv-1241; *Meda Pharmaceuticals Inc. v. L. Perrigo Company et al.*, Civil Action No. 12-cv-361; *Sepracor Inc. et al. v. L. Perrigo Company et al.*, Civil Action No. 7-cv-5136; and *Schering Corporation v. L. Perrigo Company et al.*, Civil Action No. 6-cv-4715.

17. Perrigo Company has admitted to, consented to, or has not contested the jurisdiction of this Court in at least eight prior District of New Jersey actions: *Reckitt Benckiser, LLC v. Perrigo Company et al.*, Civil Action No. 15-cv- 2156; *AstraZeneca AB et al. v. Perrigo Company et al.*, Civil Action No. 15-cv-1057; *Senju Pharmaceutical Co., Ltd. et al. v. Perrigo Company et al.*, Civil Action No. 15-cv-337; *Meda Pharmaceuticals Inc. v. Perrigo Company et al.*, Civil Action No. 14-cv-1241; *Dow Pharmaceutical Sciences, Inc. et al. v. Perrigo Company*

*et al.*, Civil Action No. 13-cv-6922; *Meda Pharmaceuticals Inc. v. Perrigo Company et al.*, Civil Action No. 12-cv-361; *Sepracor Inc. et al. v. Perrigo Company et al.*, Civil Action No. 7-cv-5136; and *Schering Corporation v. Perrigo Company et al.*, Civil Action No. 6-cv-4715.

18. Perrigo Israel has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Meda Pharmaceuticals Inc. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 14-cv-1241; *Dow Pharmaceutical Sciences, Inc. et al. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 13-cv-6922; and *Meda Pharmaceuticals Inc. v. Perrigo Israel Pharmaceutical, Ltd. et al.*, Civil Action No. 12-cv-361.

19. L. Perrigo has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least five prior District of New Jersey actions: *AstraZeneca AB et al. v. Perrigo Company et al.*, Civil Action No. 15-cv-1057; *Meda Pharmaceuticals Inc. v. L. Perrigo Company et al.*, Civil Action No. 14-cv-1241; *Meda Pharmaceuticals Inc. v. Perrigo Company et al.*, Civil Action No. 12-cv-361; *Sepracor Inc. et al. v. L. Perrigo Company et al.*, Civil Action No. 7-cv-5136; and *Schering Corporation v. L. Perrigo Company et al.*, Civil Action No. 6-cv-4715.

20. Perrigo Company has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least five prior District of New Jersey actions: *AstraZeneca AB et al. v. Perrigo Company et al.*, Civil Action No. 15-cv-1057; *Meda Pharmaceuticals Inc. v. Perrigo Company et al.*, Civil Action No. 14-cv-1241; *Meda Pharmaceuticals Inc. v. Perrigo Company et al.*, Civil Action No. 12-cv-361; *Sepracor Inc. et al. v. Perrigo Company et al.*, Civil Action No. 7-cv-5136; and *Schering Corporation v. Perrigo Company et al.*, Civil Action No. 6-cv-4715.

21. Perrigo knows or should know that Onexton® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in Onexton®'s label and prescribing information.

22. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

**THE PATENT IN SUIT**

23. The U.S. Patent and Trademark Office ("PTO") issued the '434 patent on October 16, 2012. The '434 patent claims, *inter alia*, formulations of benzoyl peroxide, including formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the '434 patent and have the right to sue for infringement thereof. A copy of the '434 patent is attached hereto as Exhibit A.

24. The PTO issued the '704 patent on November 29, 2016. The '704 patent claims, *inter alia*, formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the '704 patent and have the right to sue for infringement thereof. A copy of the '704 patent is attached hereto as Exhibit B.

25. Dow is the holder of New Drug Application ("NDA") No. 050819 for Onexton®, which the FDA approved on November 24, 2014. In conjunction with NDA No. 050819, the '434 patent and the '704 patent are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

26. Benzoyl peroxide and clindamycin phosphate topical gel (3.75%; Eq. 1.2% Base) is sold in the United States under the trademark Onexton®.

**PERRIGO'S INFRINGING ANDA SUBMISSION**

27. Upon information and belief, Perrigo filed or caused to be filed with the FDA

ANDA No. 209610, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

28. Upon information and belief, Perrigo's ANDA No. 209610 seeks FDA approval to sell in the United States Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton®.

29. Dow received letters dated December 21, 2016, and January 18, 2017, from Perrigo UK, purporting to be a Notice of Certification for ANDA No. 209610 ("Perrigo's notice letters") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

30. Perrigo's notice letters allege that Perrigo has submitted to the FDA ANDA No. 209610 seeking FDA approval to sell Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton®.

31. Perrigo's notice letters, which are required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, do not allege non-infringement of claims 1, 4-18, 41, and 44-58 of the '434 patent and claims 1-6 and 9-15 of the '704 patent.

32. Upon information and belief, ANDA No. 209610 seeks approval of Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel that is the same, or substantially the same, as Onexton®.

33. Upon information and belief, Perrigo UK's actions relating to ANDA No. 209610 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Perrigo Company.

**COUNT I AGAINST PERRIGO**

**Infringement of the ’434 Patent under § 271(e)(2)**

34. Paragraphs 1-33 are incorporated herein as set forth above.

35. Under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the ’434 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209610 seeking approval for the commercial marketing of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the ’434 patent.

36. Upon information and belief, Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the ’434 patent.

37. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’434 patent.

**COUNT II AGAINST PERRIGO**

**Declaratory Judgment of Infringement of the ’434 Patent**

38. Paragraphs 1-37 are incorporated herein as set forth above.

39. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

40. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

41. Perrigo has made, and will continue to make, substantial preparation in the United

States to manufacture, use, offer to sell, sell, and/or import Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '434 patent, including Perrigo's filing of ANDA No. 209610.

42. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 patent.

43. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel will constitute infringement of at least one claim of the '434 patent.

## COUNT III AGAINST PERRIGO

### Infringement of the '704 Patent under § 271(e)(2)

44. Paragraphs 1-43 are incorporated herein as set forth above.

45. Under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the '704 patent by submitting, or causing to be submitted to the FDA, ANDA No. 209610 seeking approval for the commercial marketing of Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '704 patent.

46. Upon information and belief, Perrigo's generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the '704 patent.

47. Upon information and belief, Perrigo will, through the manufacture, use, import, offer for sale, and/or sale of Perrigo's generic benzoyl peroxide and clindamycin phosphate

topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’704 patent.

## COUNT IV AGAINST PERRIGO

### Declaratory Judgment of Infringement of the ’704 Patent

48. Paragraphs 1-47 are incorporated herein as set forth above.

49. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

50. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

51. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the ’704 patent, including Perrigo’s filing of ANDA No. 209610.

52. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’704 patent.

53. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel will constitute infringement of at least one claim of the ’704 patent.

## PRAYER FOR RELIEF

**WHEREFORE,** Plaintiffs respectfully request that the Court enter judgment in their favor and against Perrigo on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the ’434 patent by submitting or causing to be submitted ANDA No. 209610 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the ’434 patent;

2. enter judgment that, under 35 U.S.C. § 271(e)(2), Perrigo has infringed at least one claim of the ’704 patent by submitting or causing to be submitted ANDA No. 209610 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the ’704 patent;

3. order that that the effective date of any approval by the FDA of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel be a date that is not earlier than the expiration of the ’434 patent and the ’704 patent, or such later date as the Court may determine;

4. enjoin Perrigo from the commercial manufacture, use, import, offer for sale, and/or sale of Perrigo’s generic benzoyl peroxide and clindamycin phosphate topical gel until expiration of the ’434 patent and the ’704 patent, or such later date as the Court may determine;

5. enjoin Perrigo and all persons acting in concert with Perrigo from seeking, obtaining, or maintaining approval of Perrigo’s ANDA No. 209610 until expiration of the ’434 patent and the ’704 patent;

6. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

7. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: February 3, 2017
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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**CERTIFICATION OF NON-ARBITRABILITY**
**PURSUANT TO LOCAL CIVIL RULE 201.1(d)**

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

s/ William P. Deni, Jr.
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Dated: February 3, 2017
Newark, New Jersey